510(k) Summary

Date Prepared:	July 19, 2013
Company:	Surgical Specialties Corporation, dba Angiotech 100 Dennis Dr. Reading, PA 19606
Contact:	Kirsten Stowell Regulatory Affairs Manager Phone: 610-404-3367 Fax: 610-404-3924 Email: kstowell@angio.com

AUG 2 3 2013

Device trade name:	Quill™ PDO Knotless-Tissue Closure Device, Variable Loop Design (Polydioxanone)
Device Common Name:	Polydioxanone Absorbable Surgical Suture
Device classification:	Absorbable polydioxanone surgical suture Product code, NEW 21 CFR 878.4840 Class II
Legally marketed device to which the device is substantially equivalent:	K113744 Quill™ PDO Knotless Tissue-Closure Device, Variable Loop Design, Size -0- K123877 Quill™ PDO Knotless Tissue-Closure Device, Variable Loop Design, Size 2-0 and 3-0
Description of the device:	The Quill™ PDO Knotless Tissue-Closure Device, Variable Loop Design (Polydioxanone) is a sterile, synthetic absorbable tissue-closure device that is intended for use in the closure of soft tissue. It is comprised of polyester [poly (p-dioxanone)], dyed with D&C Violet No. 2. The instrument is designed with small uni-directional barbs along the long axis of the suture monofilament which contains a welded primary loop and secondary loop design at the distal end. It is available in diameter Size 2 through 3-0 in various lengths affixed to various needle types.
Indications for Use:	Quill™ PDO Knotless Tissue-Closure Device comprised of Polydioxanone is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Substantial Equivalence:

The Quill™ Knotless Tissue-Closure Device, Variable Loop Design (Polydioxanone) has the same design and materials as the Quill™ PDO Knotless Tissue-Closure Device predicate device, including the same intended use and technological characteristics as the predicate device. The only difference between the proposed and predicate device is the suture diameter.

Performance tests:

Non-clinical laboratory performance testing was conducted to confirm that the Quill™ PDO Knotless Tissue-Closure device, Variable Loop Design (Polydioxanone), conforms to the USP monograph for absorbable sutures for tensile strength (as applicable) and needle attachment. This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003. Additional performance testing was conducted in order to demonstrate substantial equivalence to the predicate device including *in vitro* post-hydrolysis tensile testing.

The results of this testing demonstrates that the Quill™ PDO Knotless Tissue-Closure device, Variable Loop Design (Polydioxanone), is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 23, 2013

Kirsten Stowell
Regulatory Affairs Manager
Surgical Specialties Corporation, dba Angiotech
100 Dennis Drive
Reading, Pennsylvania 19606

Re: K132268
Trade/Device Name: Quill PDO Knotless-Tissue Closure Device, Variable Loop Design (Polydioxanone)
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: July 26, 2013
Received: July 29, 2013

Dear Ms. Stowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510k number if known: K132268

Device Name: Quill™ PDO Knotless Tissue-Closure Device, Variable Loop Design Polydioxanone

Indications for Use:

Quill™ PDO Knotless Tissue-Closure Device comprised of Polydioxanone, is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132268